

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 09/827,266  
Filing Date: April 5, 2001  
Applicant: James G. Skakoon et al.  
Group Art Unit: 3737  
Examiner: A.L. Lauritzen  
Title: Medical Device Introducer  
Attorney Docket: 50741-000005/US/01

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Director of the United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. COPIES

A. ☒ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office; (iii) each unpublished U.S. application listed below in Section IV (i.e., including the specification, claims, and any drawing of the application, or that portion of the application which caused it to be listed, including any claims directed to that portion), except for such applications filed on or after June 30, 2003, pursuant to the Waiver of the Copy Requirement in 37 C.F.R. 1.98 (OG Notice dated October 19, 2004); and (iv) all other information or that portion which caused it to be listed.

B. ☐ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. ☐ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search report are listed on the attached Form 1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g).)

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. ☒ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ☐ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ☐ See the attached foreign patent office communication from a counterpart foreign application:

2. ☐ English translations are provided:

3. ☐ Other:

C. ☒ The following additional information is provided for the Examiner's consideration.

International Search Report and Written Opinion for PCT/US05/43651 mailed May 8, 2008, which claims the benefit of U.S. Serial No. 11/005,607, filed December 4, 2004; and identified in Section IV of this Supplemental Information Statement.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ☒ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does (do) not waive the confidentiality provisions of 35 U.S.C. § 122.

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
11/768,065	June 25, 2007	Skakoon et al.
11/768,077	June 25, 2007	Skakoon et al.
11/768,554	June 26, 2007	Skakoon et al.
11/768,741	June 26, 2007	Skakoon et al.
11/768,760	June 26, 2007	Skakoon et al.
10/894,958	July 20, 2004	Parmer et al.
11/005,907	December 6, 2004	Skakoon et al.
10/325,615	December 20, 2002	Solar
10/370,083	February 20, 2003	Solar et al.
10/370,090	February 20, 2003	Mazzocchi et al.
11/381,647	May 4, 2006	Mazzocchi et al.
11/381,659	May 4, 2006	Solar
11/738,893	April 23, 2007	Mazzocchi et al.
11/005,605	December 4, 2004	Miller et al.
11/005,607	December 4, 2004	Solar et al.
11/262,298	October 28, 2005	Skakoon

V. THIS IDS IS BEING FILED UNDER

A. ☐ **37 C.F.R. § 1.97(b):** (check only one box)

- ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.
- ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.
- ☐ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. ☐ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ☒ **37 C.F.R. § 1.97(c):** (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. ☒ See the certification below. No fee is required.

C. ☐ **37 C.F.R. § 1.97(d):**

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. ☐ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. ☒ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. 1.704(d) below in section VII, if applicable; or

For the purpose of this certification, Applicant(s) interprets "counterpart foreign application" to mean any communication from a foreign patent office in a foreign application that claims the benefit of the subject application or any of the related patent applications cited in Section IV herein.

B. ☐ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. ☐ some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 C.F.R. 1.704(d)

The undersigned hereby states that:

☒ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box, if applicable)

A. ☐ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. ☐ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-identified fee. A duplicate copy of this paper is attached.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Respectfully submitted,

Dated: June 6, 2008  
Harness, Dickey & Pierce, P.L.C.  
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Bloomfield Hills, Michigan 48303  
(248) 641-1600

By: Richard W. Warner  
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